



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0623]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Cosmetic Registration Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice invites comments on the collection of information associated with our Voluntary Cosmetic Registration Program (VCRP).

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850,

[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Voluntary Cosmetic Registration Program--21 CFR Parts 710 and 720 (OMB Control Number  
0910-0027)--Extension

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) provides us with the authority to regulate cosmetic products in the United States. Cosmetic products that are adulterated under section 601 of the FD&C Act (21 U.S.C. 361) or misbranded under section 602 of the FD&C Act (21 U.S.C. 362) may not be distributed in interstate commerce. We have developed the VCRP to assist us in carrying out our responsibility to regulate cosmetics.

In 21 CFR part 710, we request that establishments that manufacture or package cosmetic products register with us on Form FDA 2511 entitled “Registration of Cosmetic Product Establishment.” The term “Form FDA 2511” refers to both the paper and electronic versions of the form. The electronic version of Form FDA 2511 is available on our VCRP Web site at <http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/VoluntaryCosmeticsRegistrationProgramVCRP/OnlineRegistration/default.htm>. We strongly encourage electronic registration of Form FDA 2511 because it is faster and more convenient. A registering facility will receive confirmation of electronic registration, including a registration number, by email, usually within 7 business days. The online system also allows for amendments to past submissions.

Because registration of cosmetic product establishments is not mandatory, voluntary registration provides us with the best information available about the locations, business trade names, and types of activity (manufacturing or packaging) of cosmetic product establishments. We place the registration information in a computer database and use the information to generate mailing lists for distributing regulatory information and for inviting firms to participate in workshops on topics in which they may be interested. We also use the information for

estimating the size of the cosmetic industry and for conducting onsite establishment inspections. Registration is permanent, although we request that respondents submit an amended Form FDA 2511 if any of the originally submitted information changes.

In part 720 (21 CFR part 720), we request that firms that manufacture, pack, or distribute cosmetics file with us an ingredient statement for each of their products. Ingredient statements for new submissions (§§ 720.1 through 720.4) are reported on Form FDA 2512, “Cosmetic Product Ingredient Statement,” and on Form FDA 2512a, a continuation form. Amendments to product formulations (§ 720.6) also are reported on Forms FDA 2512 and FDA 2512a. When a firm discontinues the commercial distribution of a cosmetic, we request that the firm file Form FDA 2514, “Notice of Discontinuance of Commercial Distribution of Cosmetic Product Formulation” (§§ 720.3 and 720.6). If any of the information submitted on or with these forms is confidential, the firm may submit a request for confidentiality under § 720.8.

FDA’s online filing system is available on FDA’s VCRP Web site at <http://wcms.fda.gov/FDAgov/Cosmetics/GuidanceComplianceRegulatoryInformation/VoluntaryCosmeticsRegistrationProgramVCRP/OnlineRegistration/default.htm>. The online filing system contains the electronic versions of Forms FDA 2512, 2512a, and 2514, which are collectively found within the electronic version of Form FDA 2512.

We place cosmetic product filing information in a computer database and use the information for evaluation of cosmetic products currently on the market. Because filing of cosmetic product formulations is not mandatory, voluntary filings provide us with the best information available about cosmetic product ingredients and their frequency of use, businesses engaged in the manufacture and distribution of cosmetics, and approximate rates of product discontinuance and formula modifications. The information assists our scientists in evaluating

reports of alleged injuries and adverse reactions from the use of cosmetics. We also use the information in defining and planning analytical and toxicological studies pertaining to cosmetics.

Information from the database is releasable to the public under our compliance with the Freedom of Information Act. We share nonconfidential information from our files on cosmetics with consumers, medical professionals, and industry.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

21 CFR Section or Part	Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Part 710 (registrations)	FDA 2511 <sup>2</sup>	81	1	81	0.2	16
720.1 through 720.4 (ingredient statements for new submissions)	FDA 2512 <sup>3</sup>	4,877	1	4,877	0.33	1,609
720.6 (amendments)	FDA 2512	1,042	1	1,042	0.17	177
720.6 (notices of discontinuance)	FDA 2512	1,826	1	1,826	0.1	183
720.8 (requests for confidentiality)		1	1	1	2.0	2
Total						1,987

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> The term "Form FDA 2511" refers to both the paper Form FDA 2511 and electronic Form FDA 2511 in the electronic system known as the Voluntary Cosmetic Registration Program, which is available at <http://wcms.fda.gov/FDAgov/Cosmetics/GuidanceComplianceRegulatoryInformation/VoluntaryCosmeticsRegistrationProgramVCRP/OnlineRegistration/default.htm>.

<sup>3</sup> The term "Form FDA 2512" refers to the paper Forms FDA 2512, 2512a, and 2514 and electronic Form FDA 2512 in the electronic system known as the Voluntary Cosmetic Registration Program, which is available at <http://wcms.fda.gov/FDAgov/Cosmetics/GuidanceComplianceRegulatoryInformation/VoluntaryCosmeticsRegistrationProgramVCRP/OnlineRegistration/default.htm>.

We base our estimate of the total annual responses on paper and electronic submissions received during calendar years 2011, 2012, and 2013. We base our estimate of the hours per response upon information from cosmetic industry personnel and our experience entering data submitted on paper Forms FDA 2511, 2512, 2512a, and 2514 into the electronic system.

We estimate that, annually, 81 establishments that manufacture or package cosmetic products will each submit 1 registration on Form FDA 2511, for a total of 81 annual responses. Each submission is estimated to take 0.2 hour per response for a total of 16.2 hours, rounded to 16. We estimate that, annually, firms that manufacture, pack, or distribute cosmetics will file 4,877 ingredient statements for new submissions on Forms FDA 2512 and FDA 2512a. Each submission is estimated to take 0.33 hour per response for a total of 1,609.41 hours, rounded to 1,609. We estimate that, annually, firms that manufacture, pack, or distribute cosmetics will file 1,042 amendments to product formulations on Forms FDA 2512 and FDA 2512a. Each submission is estimated to take 0.17 hour per response for a total of 177.14 hours, rounded to 177. We estimate that, annually, firms that manufacture, pack, or distribute cosmetics will file 1,826 notices of discontinuance on Form FDA 2514. Each submission is estimated to take 0.1 hour per response for a total of 182.6 hours, rounded to 183. We estimate that, annually, one firm will file one request for confidentiality. Each such request is estimated to take 2 hours to prepare for a total of 2 hours. Thus, the total estimated hour burden for this information collection is 1,987 hours.

Dated: January 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.